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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,213	Applicant(s) BARBERA-GUILLEM ET AL.
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,19-23,25,26,28-31,33,35-38,40,41,43-45 and 48 is/are pending in the application.
 4a) Of the above claim(s) 19,25,28,35 and 40 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,20-23,26,29,30,31,33,36-38,41,43-45,48 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-548)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/17/08 has been entered.
2. Claims 1,20-23,26,29-31,33,36-38,41,43-45,48 are under consideration.
3. Applicant is required to update the status of all US patent applications disclosed in the instant application.
4. Applicant states that this application is a continuation or divisional application of the prior-filed application. A continuation or divisional application cannot include new matter. Applicant is required to change the relationship (continuation or divisional application) to continuation-in-part because this application contains the following matter not disclosed in the prior-filed application.

There is no support in the parent applications for claim 1, lines 2-4 (or said limitation in claims 26,33,38). Regarding applicants comments, the specification, page 13 contains other limitations regarding the limitation under consideration such that the absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications. There is no support in the parent applications for claims 22,23,30,31,37,38,43,44,48. Regarding applicants comments, the specification, page 14 contains other limitations regarding the limitation under consideration such that the absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications. The specification, page 13 contains other limitations regarding the limitation under consideration such that the absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications. Regarding applicant comments about the other cited passages of the specification, none of said passages address the limitations under consideration (aka "a humoral immune response induced against an epitope comprising terminal alpha 2,6 linked sialic acid on

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shed antigen"). The description of said response on page 14 of the specification contains other limitations regarding the limitation under consideration such that the absence of said limitations broadens the scope of the claimed invention such that it lacks support in the parent applications.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The rejection of claims 1,18,20-24,26,27,29-34,36-39,41-44,45-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in paragraph 5 of the previous Office action is withdrawn in view of the amended claims and cancellation of claims that have been cancelled..

7. Claims 1,20-23,26,29-31,33,36-38,41,43-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed of the recitation of "human antibody" or "murine antibody" or "antibody containing both murine antibody region and human antibody region" in the claims. Said limitations do not find support in any of the passages cited by applicant. The specification does not disclose use of murine or human antibodies in the instant method. The specification discloses use of chimeric or humanized antibodies in the claimed invention, but does not disclose use of murine or human antibodies. The specification does not disclose "antibody containing both murine antibody region and human antibody region" because said term would encompass antibodies other than the chimeric or humanized antibodies disclosed in the specification such as antibodies with chimeric Fc receptors or antibodies which used murine and human CDRs, etc.

8. Claims 1,20-23,26,29-31,33,36-38,41,43-45,48 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of claimed invention.

The claims recite use of an antibody that binds CD19, wherein said claims encompass use of antibody which binds CD19 from any animal species and wherein said antibody also binds CD19 in humans. It is unclear as to what species of CD19 were known in the art other than murine or human. The identity of CD19 from unknown species is unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred",

Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the claims recite use of an antibody that binds CD19, wherein said claims encompass use of antibody which binds **CD19 from any animal species** and wherein said antibody also binds CD19 in humans. It is unclear as to what species of CD19 were known in the art other than murine or human. The identity of CD19 from unknown species is unpredictable. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. It is noted that the instant address does not address the species of the antibody, but addresses the species of CD19 recognized by the antibody (aka murine antibody that binds moose CD19, wherein the antibody cross reacts with human CD20). The issue could be addressed by amending the claims to recite "human CD19", etc.

9. The rejection of claims 1,18,20-24,26,27,29-34,36-39,41-44,46-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for

the reasons elaborated in paragraph 8 of the previous Office is withdrawn in view of the amended claims and cancellation of claims that have been cancelled.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 21,29,36,41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21,29,36,41 are indefinite in that the composition recited in the claims from which they depend is closed (composition consisting of), yet said claims add additional ingredients. In addition, "contains" is open in scope (equivalent in scope to comprising) and therefore the composition is broader in scope in said claims than the claim from which it depends.

12. Regarding the application of prior art and priority to parent applications, for the same reason that claims lack written description or description in the parent applications, they are not entitled to priority to the parent application to which priority is claimed.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1,20-23,33,36-38,41,43-45,48 stand rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (EP 0332865). Applicants arguments have been considered and deemed not persuasive.

According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Meyer et al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells.

Regarding applicants comments, the claimed methods recite "comprising administering" and therefore encompass the administration of agents in addition to the antibodies recited in the claims. Furthermore, as per paragraph 11 of the instant Office action, the composition recited in the claims can contain additional ingredients. Regarding applicants comments, whilst the elected species is CD19, the claims recite use of Lym-1 antibody. The art rejection addresses use of Lym-1 antibody as per recited in the claims. Regarding applicants comments about other antibodies that are administered by Meyer et al., the claims are open in scope and encompass the administration of other antibodies in combination with the anti Lym-1 antibody. According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Thus, said response is found in MS patients, wherein the claimed method therefore encompasses treatment of MS patients with the particular antibodies recited in the claims. Meyer et

al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1,20-23,33,36-38,41,43-45,48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (EP 0332865) in view of Pesando (WO 91/13974) and Aruffo et al (US Pat. No. 6,051,228). Applicants arguments have been considered and deemed not persuasive.

According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Meyer et al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells. Meyer et al. does not disclose use of antiCD19 antibody in said method. Pesando discloses use of antiCD19 antibodies (which bind CD19 positive B cells) to treat autoimmune diseases (see page 4, penultimate paragraph). Aruffo et al. teach a method of treating the autoimmune disease multiple sclerosis (MS) by administering a chimeric antibody to the CD40 antigen (see entire document, e.g., columns 21-22 and in particular column 21 at lines 25-31). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Meyer et al. teach the claimed methods except for use of antiCD19 antibody whilst Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases. One of ordinary skill in the art would have been motivated to do the aforementioned because Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases whilst Aruffo et al. disclose that MS is an autoimmune disease.

Applicants comments regarding Meyer et al. and the scope of the claims are addressed above. Regarding applicants comments about Aruffo et al., as per applicants comments CD40 is expressed **on B cells**. Pesando discloses use of antiCD19 antibodies (which bind CD19 positive B cells) to treat autoimmune diseases (see page 4, penultimate paragraph). Aruffo et al. merely establishes that MS is an autoimmune disease.

Regarding applicants unsupported comments about what was well known in the prior art, the MPEP section 716.01(c) [R-2] states:

>II. < ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Regarding applicants comments about other antibodies that are administered by Meyer et al., the claims are open in scope and encompass the administration of other antibodies in combination with the anti Lym-1 antibody. According to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. Therefore, patients with MS would have said response. Thus, said response is found in MS patients, wherein the claimed method therefore encompasses treatment of MS patients with the particular antibodies recited in the claims. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Meyer et al. teach treatment of progressive MS with the antib cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells. Regarding applicants comments about Pesando, Pesando discloses use of antiCD19 antibodies (which bind CD19 positive B cells) to treat autoimmune diseases (see page 4, penultimate paragraph). Applicant comments regarding the scope of the claims have been addressed above. **The current claims encompass treatment using antiCD19 in combination with other antibodies.**

Thus, Pesando already discloses that antiCD19 antibody could be used to treat autoimmune disease. Aruffo et al. teach a method of treating the autoimmune disease multiple sclerosis (MS) by administering a chimeric antibody. In view of the aforementioned teachings it would have been obvious to use the antiCD19 antibody as

per taught by Pesando to treat the autoimmune disease MS, especially in light of the teachings of Meyer et al. that progressive MS can be treated with antiB cell antibody. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that "**if a technique has been used to improve one device , and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill**". Meyer et al. teach treatment of progressive MS with the antiB cell antibody Lym-1 in a pharmaceutically acceptable carrier (see page 3) via injection (see Example 9) . Meyer et al. disclose that said antibody is used to deplete mature B cells (see page 3, third paragraph, wherein the antibody does not recognize stem cells, thus allowing for a later repopulation of B-lymphocytes (aka the mature B cells have been depleted)). Depletion of B cells would result in reduction of responses mediated by B cells. Meyer et al. does not disclose use of antiCD19 antibody in said method. Pesando discloses use of antiCD19 antibodies (which bind CD19 positive B cells) to treat autoimmune diseases (see page 4, penultimate paragraph). Aruffo et al. teach a method of treating the autoimmune disease multiple sclerosis (MS) by administering a chimeric antibody to the CD40 antigen (see entire document, e.g., columns 21-22 and in particular column 21 at lines 25-31). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Meyer et al. teach the claimed methods except for use of antiCD19 antibody whilst Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases. One of ordinary skill in the art would have been motivated to do the aforementioned because Pesando discloses use of antiCD19 antibodies to treat autoimmune diseases whilst Aruffo et al. disclose that MS is an autoimmune disease. Regarding applicants comment about the pro-MS response, according to the specification, page 3, last paragraph , the pro-MS immune response recited in the claims causes MS and is found in MS patients. In addition, said response is also disclosed in the specification as responsible for clinical manifestations of progressive MS (see page 4, last paragraph and page 14, last paragraph). Thus, said response would be found in progressive MS/MS patients.

16. Claims 20,26,29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (EP 0332865) in view of Pesando (WO 91/13974) and Aruffo et al (US Pat. No. 6,051,228) as applied to claims 1,20-23,33,36-38,41,43-45,48 above, and further in view of Turk et al.

The previous rejection renders obvious the claimed invention except for delivery of the antibody into an access that directly supplies central nervous system tissue. Turk et al. disclose intrathecal (aka delivery of the antibody into an access that directly supplies central nervous system tissue) delivery of antibody for treatment of MS (see column 6, penultimate paragraph). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because the previous rejection renders obvious the claimed invention except for delivery of the antibody into an access that directly supplies central nervous system tissue whilst Turk et al. disclose intrathecal (aka delivery of the antibody into an access that directly supplies central nervous system tissue) delivery of antibody for treatment of MS.

Regarding applicants comments, Turk et al. disclose intrathecal (aka delivery of the antibody into an access that directly supplies central nervous system tissue) delivery of antibody for treatment of MS (see column 6, penultimate paragraph). Thus, use of intrathecal antibody treatment for treating MS was known in the art. In KSR Int'l Co. v. Teleflex Inc., 550 U.S. m, 2007 WL 1237837, at "13 (2007) it was stated that "**if a technique has been used to improve one device , and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill**". Applicants other comments are as per addressed above.

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./
Primary Examiner,
Art Unit 1644